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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,663	03/14/2002	Nelson D. Horseman	AVI021	2987
7590	08/11/2004			
DAVID J. HAYZER, PH.D., J.D. WOMBLE CARLYLE SANDRIDGE & RICE, PLLC P.O. BOX 7037 ATLANTA, GA 30357-0037			EXAMINER QIAN, CELINE X	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/099,663	Applicant(s) HORSEMAN ET AL.	
	Examiner Celine X Qian	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-86 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 50-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 50-86 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 1/7/04 is acknowledged. Applicants assert that newly entered claims 50-57, 63-67 and 69-86 are drawn to the invention directed to the original Group II. Applicants further argue that the SEQ ID NO:2 is completely included within SEQ ID NO:1, hence restriction dividing the inventions according to these two sequences is improper. Therefore, Applicants conclude that the inventions of Groups I and II should be examined together.

These arguments have been fully considered and deemed partially persuasive. The inventions directed to two different sequences will be rejoined. However, the newly entered claims 50-57, 63-67 and 69-86 also encompass inventions that not part of the Group II of the original claims. For example, claims 84-86 are directed to a transgenic avian, not a nucleic acid sequence. In view of the different subjected matters encompassed by the newly entered claims, the claims are re-restricted to one of the following invention according to 35 U.S.C. 121.

Group I. Claims 50-81 and 83, drawn to an isolated nucleic acid molecule comprising an avian gut specific gene expression control region, a recombinant vector comprising said nucleic acid molecule, a cell comprising said nucleic acid molecule *in vitro*, and a method for producing a heterologous protein using said host cell, classified in class 536, subclass 24.1, class 435, subclass 320.1, 325 and 70.1.

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Group II. Claims 77-81 and 83, drawn to a eukaryotic cell transformed with the expression vector *in vivo*, and an *in vivo* method of producing a heterologous protein in said eukaryotic cell, classified in class 800, subclass 8.

Group III. Claims 82 and 84-86, drawn to a transgenic avian comprising a recombinant nucleic acid molecule comprising an avian gut-specific gene expression vector control region operably linked to a nucleic acid insert encoding a polypeptide, and a cell within the transgenic avian comprising said expression vector, classified in class 800, subclass 19.

The inventions are patentably distinct, each from the other for following reasons.

The inventions of Groups I and II are patentably distinct because the inventions are drawn to materially distinct compositions and methods that require different starting material and modes of operation. Although the nucleic acid of Group I can be used in the method of producing a heterologous protein *in vivo*, it can also be used in the method for directing the expression *in vitro*. Moreover, a method of producing a heterologous protein *in vitro* requires different starting material and involves different method steps than a method of producing a heterologous protein *in vivo*. Therefore, the invention of Groups I and II are patentably distinct.

The invention of Groups II and III are patentably distinct because the inventions are drawn to materially distinct compositions that are not related. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the cells of Group II are not capable of being used together with the transgenic avian

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of Group III, each has its distinct functions. Therefore, the inventions of Groups II and III are patentably distinct.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid and cells of Group I cannot be used together with the transgenic avian of Group III, each has its distinct function. In addition, the method of producing the heterologous protein of Group I does not require the transgenic avian of Group III, whereas the transgenic avian of Group III can be used to identify agents that regulate the gut-specific expression of a reporter gene. Therefore, the inventions of Group I and III are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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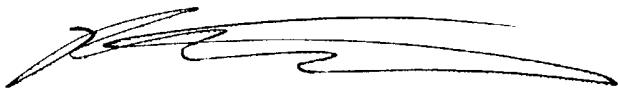
application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to be 'Celine Qian', with a long horizontal flourish extending to the right.